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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,821

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Tsunenori Arai

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

NOTIFICATION DATE

DELIVERY MODE

06/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/560,821	Applicant(s) ARAI ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 9/6/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>121505 042706 090607</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Specification***

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the term "almost not activated" is used throughout the disclosure. This still would indicate the photosensitizer is activated, making the selective activation difficult to clearly define.

Claim Objections

Claims 19-22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. No additional device structure is disclosed in the claims. Results of the use of a device do not further limit the device structure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The control means is

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enabled to control the operational parameters of the light, not a depth in a body where a photosensitizer is activated. Such activation is dependent on where the photosensitizer is located based on selective or non-selective absorption of the photosensitizer and the properties of the photosensitizer as well as the tissue characteristics through which the light must travel.

Claim 13 is not enabled as no steps for a method are positively cited.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 cites a range as "almost not activated". It is not clear how this differs from being activated.

Claim 1 recites the limitation "the wavelength" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the position" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the high peak" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the deep-lying" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the superficial part" in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the threshold" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the repetition frequency" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the high peak" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the superficial part" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the position" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the wavelength" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the photosensitive substance" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 cites a range as "almost not activated". It is not clear how this differs from being activated.

Claim 17 cites controlling the condition of the irradiation of the light. The term is not clearly defined. Controlling light parameters such as wavelength and intensity are examples of clearly defined parameters. The activation of a photosensitizer and resulting cell destruction are results of the light, not directly controlled by the control means.

Claim 19 cites "in the direction of the depth in the body is high in a corresponding part of the body". The term is confusing and unclear.

Claim 20 cites "in the direction of the depth in the body is distributed high in a corresponding part of the body". The term is confusing and unclear.

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Claims 22-25 are indefinite as the control means does not directly control the parameters cited, rather the parameters are indirect results of the light application.

Claim 29 cites a range as "almost not activated". It is not clear how this differs from being activated.

Claim 29 recites the limitation "the wavelength" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "the deep lesioned part" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 10-25 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,592,361 to Parker et al. Parker et al. disclose an apparatus for delivering photodynamic therapy with a pulsed light source (Fig. 3, # 16) having a wavelength, intensity, pulse width and pulse rate controlled by a microprocessor (Col. 12, lines 3-14). Parker et al. teach controlling the irradiation source using a detector to determine the level of oxygen available to avoid depletion that would inhibit singlet oxygen production (Col. 13, lines 25-35).

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Parker et al. disclose the light may be an Nd:YAG laser operating at a second harmonic (Col. 10, line 18).

The claims contain functional language that does not add to the structural device. All photosensitizers have an intensity at which they activate and all light has an intensity.

Claim 1 only positively claims a controlled irradiation means. Parker et al. is capable of directing light of an intensity and pulse rate at a target area. How the light behaves in the tissue is dependent on the photosensitizer used, wavelength (a primary determinate of penetration depth), intensity and tissue properties. Altering the intensity (peak intensity) is clearly part of a control process. The microprocessor control of Parker et al. is capable altering the parameters as discussed above as required by the photosensitizer being used as is well known in the arts. No specific photosensitizer characteristics are claimed, in fact, no photosensitizer is positively claimed rendering the claims regarding how it is activated indefinite as discussed above. Lacking specific structural limitations other than control means and irradiation means fails to provide finite metes and bounds and allows Parker et al. to be broadly interpreted to read on the claims.

Regarding claim 29, Parker et al. discloses detecting fluorescence from a photosensitizing dye, thus it is inherent that such would have to be administered and irradiation is clearly done with the structure disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,592,361 to Parker et al. as applied to claim 1 above and further in view of U.S. Patent Application Publication US 2003/0022105 to Prasad et al. Parker et al. are discussed above, but do not teach intensities or pulse rates. Prasad et al. discloses intensities for photodynamic therapy of from 0 to 200 MW/cm² (paragraph 0321) and pulse rates of from 0.1 Hz to 1 kHz (paragraph 0334). The basis of photodynamic therapy is the use of photosensitizers with specific properties. Prasad et al. teach photosensitizers requiring high intensities and a skilled artisan knows that small pulse widths provide the ability to produce the higher intensities. Therefore, it would have been obvious to one skilled in the art to use the high intensities and pulse rates as taught by Prasad et al. in the device of Parker et al. to properly activate the photosensitizer.

Claims 7-9 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,592,361 to Parker et al. as applied to claims 1 and 17 above and further in view of U.S. Patent 5,514,669 to Selman. Parker et al. are discussed above, but do not teach the use of a catheter for delivery of light for photodynamic treatment. Selman teaches photodynamic therapy wherein the light energy is delivered to a patient's prostate by placing the light delivery means in a urethral catheter. The light delivery means is properly located within the urethra and

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positioned adjacent to the target prostate tissue. A balloon may be affixed to the distal end of the catheter (Col. 5, lines 15-25). It would have been obvious to one skilled in the art to use the catheter as taught by Selman in the device of Parker et al. as the use of such catheters is pervasive in the arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739

/HMJ/
6/19/2008